PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/GB2004/001155	International filing date *(day/month/year)* 18.03.2004
Priority date *(day/month/year)* 18.03.2003	
International Patent Classification (IPC) or both national classification and IPC A61F2/06	
Applicant VERYAN MEDICAL LIMITED	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Franz, V Telephone No. +49 89 2399-6084

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2004/001155

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,4,5,6,13,20
	No:	Claims	1,2,7,8,9-12,14-19
Inventive step (IS)	Yes:	Claims	
	No:	Claims	3,4,5,6,13,20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1:WO00/38591 Tangential Case 1
D2: EP1269935 " Case 6
D3: US2002/0116044
D4: WO00/49973
D5: WO99/17682

lack of novelty

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claims **1** and **12** is not new in the sense of Article 33(2) PCT.

a. The document **D1** discloses (the references in parentheses applying to this document): A stent for insertion in a fluid conduit of the human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition (p. 5, l. 16-18), the stent comprising an outer wall for engagement with the conduit, the outer wall having a helical portion which in the expanded condition extends longitudinally and circumferentially (Fig. 3), and which, upon expansion of the stent from the collapsed condition to the expanded condition, resists extension (for expansion of every stent a certain resistive force has to be overcome). Thus, claim **1** is not novel.

b. The only substantially different feature of independent claim 12 in respect to claim 1 is that the helical centre line has a helix angle less than or equal to 65°. Document **D1** shows this feature (p. 9, l. 27-p. 10, l. 4) as well as the other features of claim 12, so that claim **12** lacks novelty.

c. Note that also document D2 anticipates the subject-matter of claims 1-3 and 5-19 while document D3 discloses the subject-matter of claims 1-9 (cf. International search report and the references cited therein). In particular, <u>all</u> stents with an expandability that along a certain line differs from the expandability along all other lines exhibit the features claimed in claims 1-8 because the applicant himself shows experimentally that by introducing a helical portion which resists extension during expansion of a stent, when expanded the stent will adopt a shape causing a fluid conduit which it supports to have a helical lumen (p. 23, l. 33-36 of the present application).

d. Dependent claims **2-8** and **13-20** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (claims 2, 7, 8, 14-19) or inventive step (claims 3-6, 13, 20), see documents D1-D4 and the corresponding passages cited in the search report.

Re Item VII

Certain defects in the international application

1. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 is not mentioned in the description, nor is this document identified therein.

Re Item VIII

Certain observations on the international application

1. The present application does not fulfill the requirements of Article 6 PCT because claims **1, 4, 8,** and **9** are not clear.

a. The expression used in claims **1** and **9**, that the "helical portion ... resists extension" and the expression used in claim **4** that the helical portion has "bent portions which resist unbending" are unclear because every plastic material resists deformation. It is not specified if the resistance of a certain portion is larger than the resistance of another portion.

b. Claim **8** is unclear because it is not specified which features lead to the desired result, i.e. expansion without substantial twisting.

c. Claim **9** is unclear as a whole. It refers to "a balloon expandable stent, ..., the stent comprising a balloon". It is not clear whether this is an additional balloon or the balloon for expansion of the stent. In the first case actually a stent-graft would be claimed. In the second case a helical balloon for expansion of arbitrarily shaped stents would be claimed. For both versions no support in the description was found.